OCT 2 5 2007 K071652

5.0 510(k) Summary

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Contact:	Mr. Allan White (Official Correspondent) HemoCue, Inc. 40 Empire Drive Lake Forest, CA 92630-2244 (949) 859-2630 x110 (Telephone) (949) 598-8630 (FAX) allan@hemocue.com
Date of Preparation:	June 14, 2007
Common name of device:	Semi-Automated Cell Counter
Proprietary Name:	HemoCue WBC System
Class:	Class II
Panel:	Hematology (81)
Regulation number:	Automated and Semi-Automated Hematology Devices, 21 CFR § 864.5200 Automated Cell Counter or Semi-
Automated	Cell Counter
Product Code:	GKL
Equivalent to:	HemoCue AB claims substantial equivalence to the current legally marketed device: Sysmex XS-1000*i*, Automated haematology analyzer (K060656) and Manual light microscopic WBC method (class I exempt)

5.1 Device Description

The system consists of the HemoCue WBC Analyzer together with specially designed microcuvettes, the HemoCue WBC Microcuvettes. The microcuvette serves both as a sample container and a reaction chamber. A blood sample of approximately 10 µL is drawn into the cavity by capillary action. A hemolysing agent lyses the red cells in the microcuvette and a staining agent colors the white blood cells. An image is taken of the stained white blood cells and the number of cells is counted by image analysis. The result is presented within 3 minutes on the analyzer's display. The system reports results in the measuring range 0.3 - 30.0 x10^9/L. The system is factory calibrated and needs no further calibration.

The test principle consists of three simple steps:

1. Fill the microcuvette with a drop of blood
2. Place the microcuvette in the analyzer
3. Receive a result within 3 minutes.

5.2 Indications for Use

The HemoCue WBC system is indicated for use for quantitative determination of white blood cell (WBC) count in capillary or venous whole blood. The HemoCue WBC system is for In Vitro Diagnostic use only. The HemoCue WBC Analyzer is only to be used with HemoCue WBC Microcuvettes. The HemoCue WBC system is indicated for use in clinical laboratories and for point-of-care settings.

5.3 Summary of Technological Characteristics

The HemoCue WBC Analyzer

The HemoCue WBC Analyzer (figure 1) is a portable device. The main parts are the cuvette holder (in which the microcuvette is placed), the cuvette moving arm (brings the microcuvette into correct measuring position), a magnifying optic unit, a camera, image processing software, a display and a power adapter.

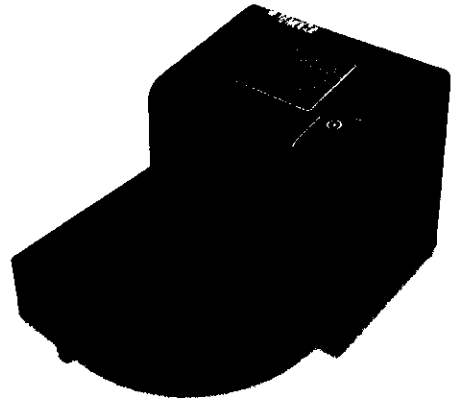

Figure 1. The HemoCue WBC Analyzer

The HemoCue WBC Microcuvette

The HemoCue WBC Microcuvette (Figure 2) is made of polystyrene plastic and contains saponin that hemolyzes the red blood cells, methylene blue that stains the white blood cells and nonactive reagents. A blood sample of approximately 10 µL is drawn into the cavity by capillary action. The microcuvette serves as a sample container and a reaction chamber. No dilution of the sample is required.

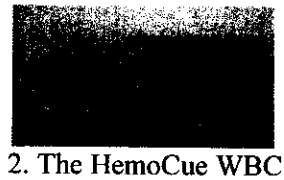

Figure 2. The HemoCue WBC Microcuvette

5.4 Similarities and Differences with Predicate Devices

The HemoCue WBC system is a semi-automated device intended for use for the quantification of White Blood Cells in clinical laboratories and point of care settings.

The Sysmex XS 1000i (predicate device) is an automated hematology analyzer for use in clinical laboratories.

Light microscopes (predicate device) are used as to enumerate leukocytes in a haemocytometer mounted on the stage of the microscope and read manually

Similarities and Differences: All three devices quantify leucocytes (WBCs), but the Sysmex XS device also quantifies red blood cells, platelets, hemoglobin, hematocrit and provides a differential cell count.

5.5 Assessment of Performance

Studies were conducted in-house, in clinical laboratory settings and point of care settings to demonstrate the performance with intended specifications of the HemoCue WBC system and to validate that the intended user can easily operate the system and obtain results as expected.

5.6 Conclusion

Based on the information and performance data presented in this premarket notification, the HemoCue WBC system meets the manufacturer's intended use specifications and is substantially equivalent to the Sysmex XS-system and the manual light microscopic method of counting WBC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 25 2007

Hemocue AB
Hemocue Inc.
c/o Allan White
40 Empire Drive
Lake Forest, California 92630

Re: k071652
Trade/Device Name: Hemocue WBC System
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated cell counter
Regulatory Class: Class II
Product Code: GKL
Dated: June 14, 2007
Received: June 18, 2007

Dear Mr. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4.0 Statement of Indications of Use

510(k) Number: K071652

Device Name: HemoCue® WBC system

Indications For Use:

The HemoCue WBC system is indicated for use for quantitative determination of white blood cell (WBC) count in capillary or venous whole blood. The HemoCue WBC system is for In Vitro Diagnostic use only. The HemoCue WBC Analyzer is only to be used with HemoCue WBC Microcuvettes. The HemoCue WBC system is indicated for use in clinical laboratories and for point-of-care settings.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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